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The attached photocopy is a true copy of the following document:

- The specification, claims, abstract and drawings as filed with the application on the filing date indicated above.

Erhvervsministeriet  
Patentdirektoratet

TAASTRUP 05 Oct 1999

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23 SEP. 1998

**TITLE**

Catheter set.

**FIELD OF THE INVENTION**

The present invention relates to a catheter set comprising a catheter and a  
5 package for both storing of the catheter before use and for collecting or  
discharging urine.

**BACKGROUND OF THE INVENTION**

Urinary catheter sets comprising a catheter having a hydrophilic coating, a  
wetting receptacle and a wetting fluid are disclosed in WO publication No.  
10 98/11932 (Coloplast A/S) and in WO publication no. 97/26937 (Astra Aktiebolag)

Both publications describe catheter sets comprising both a catheter and a  
package, and in both publications an elongated part of the package forms a tube  
and is used for leading urine either to the inside of the package for later disposal  
or to an exterior container e.g. a toilet bowl for immediate disposal.

15 The use of such catheter sets is described by referring to figure 1 of WO  
97/26937. First the proximal portion of the pocket 2 is torn off and the elongate  
shaft 18 of the catheter 3 is manoeuvred through the opening in the proximal end  
of the pocket 2 and into the urethra of the patient until a flared distal portion 16  
forms a mechanical seal connection with the opening. Urine in the bladder of the  
20 patient is transported through the lumen of the catheter 3 into the urine collection  
chamber 12. After emptying the bladder the catheter 3 is manoeuvred back  
inside the bag 1 and the open end of the pocket 2 closed off for example by tying  
a knot with the material defining the pocket 2 or clamping the pocket with a  
clamp.

25 A disadvantage with these catheter sets is that the mechanical seal connection  
between the flared distal portion of the catheter and the proximal part of the  
package does not always work properly and the result is that urine flows  
backward and out of the package, especially due to restriction of the flow from

the catheter into the receptacle due to folding, twisting or kinking of the elongated part of the device leading from the catheter to the receptacle..

The object of the invention is to solve this problem and provide a catheter set preventing the risk of spilling urine over cloth or surroundings when performing  
5 intermittent catheterisation, especially when performed by the patient himself, and at the same time to provide a catheter set which is simple and inexpensive to produce. It has surprisingly been found that the above drawbacks may be overcome using a catheter set according to the invention.

#### **BRIEF DESCRIPTION OF THE INVENTION**

10 The present invention relates to a catheter set comprising a catheter and a package for both storing of the catheter before use and for collecting or discharging urine.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

The invention will be explained more in detail with reference to the accompanying  
15 drawings showing embodiments of the invention and in

Fig. 1 shows an embodiment of a catheter set according to the invention,  
Fig. 2 shows the embodiment of Fig. 1 ready for use,  
Fig. 3 shows another embodiment of a catheter set according to the invention,  
Fig. 4 shows a sealing system according to the invention in an enlarged scale,  
20 and  
Fig. 5 shows the embodiment of Fig. 3 in a sealed state.

#### **DETAILED DESCRIPTION OF THE INVENTION**

The present invention relates to a catheter set comprising a catheter and a package for storing of the catheter before use and for collecting or discharging  
25 urine, said catheter set being characterised in that the catheter has a proximal part to be inserted into the urethra and a distal part in the form of a tubular section having an inner diameter at least as large as the inner diameter of the part of the proximal part of the catheter.

When in use, the distal tubular part of the catheter of the invention reaches into the upper part of the package and keeps the front and rear parts thereof apart and thus prevents a blocking of the free flow of urine from the urethra into the package. In the absence of the tubular part, urine flowing through the catheter  
5 may meet an obstacle if for example the package is folded or squeezed and thus, the urine will fill up the upper part of the package and establish a back pressure on the sealing between the catheter and the package. When a tubular part of the catheter is inside the package as an extension of the catheter it thus prevents the flow of urine from being disturbed in the upper part of the relatively  
10 soft package, and the flow of urine will be directed downwards until the package is full. The inner diameter of the tubular part of the catheter must be of at least of the same dimension as the proximal part of the in order not to hamper the free flow of urine from the bladder through the catheter and into the package.

The tubular part of the catheter may be a prolonged part of the catheter itself or  
15 a separate tubular piece which is connected to the catheter.

In a preferred embodiment of the invention the proximal part of the catheter has a hydrophilic coating. A hydrophilic coating may be any hydrophilic coating known per se for use for hydrophilic coated catheters and the coating may be applied using any method known per se for applying a hydrophilic coating to a  
20 catheter.

The catheter set according to the invention preferably comprises a wetting fluid integrated into the package in order to enable activation of a hydrophilic coating irrespectively of the access to pure water. The wetting fluid may be sterilised water or saline.

25 It is preferred that the catheter comprises a sealing part for providing a seal between the catheter and the package during use. A sealing part may e.g. be a part of the catheter having an increased diameter. Such a sealing part will also function as a stop preventing the catheter from falling out of the package and, at the same time function as a seal during use preventing spilling of urine during  
30 catheterisation.

It is very practical when the sealing part is separating the proximal part of the catheter and the tubular distal part as this provides safety against trying to insert the tubular part into the urethra and also ensures that the tubular part remains in the package for ensuring the free flow of urine into the package.

- 5 In one embodiment of the invention the tubular distal part of the catheter has an inner diameter larger than the inner diameter of the proximal part of the catheter. Thus, no extra resistance against the flow will occur and, as the outer diameter thereof is consequently also greater, the transition between the two parts of the catheter may function as a stop and sealing.
- 10 In this embodiment the tubular part of the catheter may e.g. be in the form of a telescopically extendible tube having a maximum diameter greater than the proximal part of the catheter. Alternatively, the tubular part may be in the form of an extendible corrugated tubing resembling a corrugated straw which may be folded, compressed or stretched like an accordion.
- 15 The tubular part of a catheter is preferably made from an extrudable, mouldable material such as a polyolefin such as polyethylene (PE) or polypropylene (PP) or a copolymer of polyethylene such as ethylene vinyl acetate (EVA) or polyvinyl chloride (PVC) or polyvinylidene chloride or a polyurethane (PU) or a silicone. It is envisaged that the proximal and distal tubular part of the catheter and the
- 20 sealing part may be produced as an integrated unit from the same material by a combination of injection moulding, extrusion and/or blowing.

- It is preferred when the tubular distal part of the catheter is transversely corrugated as this adds to the security against kinking. A suitable flexible and transversely corrugated tube is known per se for preventing blocking by bending of
- 25 the tube leading to urine collection bags.

In accordance with a preferred embodiment of the catheter set of the invention the package has an elongated narrow part designed for the exit of the catheter and a broader container part for collecting the urine.

In accordance with another preferred embodiment of the invention the package is provided with one or more sealing devices on the exterior side of the package designed for holding and sealing the elongated end of the package after use.

When using the package for collecting urine, it is possible to tie a knot on the  
 5 elongated part after pushing the catheter into the package but this still leaves a small amount of urine in the outer part of the package which may be spilled onto the clothes which will be embarrassing for the user.

The sealing device is preferably in the form of an adhesive sheet adhered to the package. The sheet may typically comprise a sheet of a relatively soft and pliable  
 10 material having an adhesive on the surface facing the outer side of the package and wherein a part of this surface is covered with a release liner which is adhered to the outer surface of the package. Thus, the sheet functions as a part of the surface of the package when not in use, and when used, the sheet is released from the release liner, which is then removed, and the top of the bag is  
 15 preferably placed at the adhesive area and the sheet is placed at the adhesive area holding and sealing the end of the bag.

The sealing device of this embodiment securely closes and seals the opening of the package and furthermore, it enables a sealing by bending the top of the package and securing and sealing the same below a flap of an adhesive sheet  
 20 adhered to the package the sealing device without having to push the catheter into the package which facilitates the sealing and provides a better security against spilling of urine.

The sheet may be of any suitable material e.g. the ones mentioned above. The adhesive may be any suitable adhesive being compatible with the package  
 25 material and the sheet material. It is preferred when the adhesive exhibit some moisture absorbing capability in order to ensure a secure sealing even if some drops of urine are spilled when sealing the top of the package after use. An moisture absorbing adhesive may be any such adhesive known per se for wound or ostomy purposes, e.g. containing hydrocolloids.

30 A release liner may for instance be siliconized paper.

The package may be made from a water impervious layer or film of any suitable material known per se for use in the preparation of urine collection bags.

The length of the tubular part may vary according to the specific application. Of course, it should not be so long that it cannot be comprised in the bag. Even at  
 5 small lengths of the tubular part an effect is obtained. In a preferred embodiment the tubular part has a length at least corresponding to the narrow upper part of the package.

#### DETAILED DESCRIPTION OF DRAWINGS

Reference is made to Fig. 1. The embodiment of the catheter set of the invention  
 10 shown in Fig.1 comprises a catheter 1, a package 2 for collection of urine, a sealing part 3 and a flexible tubular part 4 connected to the catheter 1. The top of the package is easily torn off at 5 being a weak point for breaking the package. Furthermore, the package comprises another weak point 6 designed for opening the package at the distal end, if desired, during use, if the package is to function  
 15 as guide to e.g. a toilet bowl or after use if it is desired to empty the bag immediately. The package is shown with an ear 7 for an easy handling of the package during and after use. Furthermore, a container 8 is shown comprising a wetting fluid.

In Fig. 2 the embodiment of Fig. 1 is shown after opening the container and  
 20 wetting the catheter and tearing off the top of the package and pushing the catheter until the stop engages with the bag ready for insertion. The insertion may, if desired, be performed concomitantly with the pushing out of the catheter.

When the catheter is in use the urine flows in through the openings in the upper part - the proximal end - of the catheter 1 and enters the inside of the package 2  
 25 where it passes through the upper part which, in this embodiment, is in the form of a narrow portion as compared to the lower part of the package which is formed as a broader collection part. When the urine is passing the upper part of the package 2 it also passes the flexible tubular part 4 which is present inside this part of the package and secured to the catheter 1. The flexible tube 4  
 30 provides the package with a certain stiffness which prevents blocking of this part

by kinking or squeezing of the relatively soft and pliable package 2. In the figure the flexible tube is shown as a smooth tube but it might as well have a corrugated surface. The most important features for the tube is that it has to be both bendable and in possession of a certain stiffness.

- 5 When the user has finished the use of the catheter he can either throw the used catheter and the filled or urine contaminated package away immediately or he can close the package and transport it to the nearest convenient waste container if there are not any present at the facility.

- The user might experience a problem trying to close the package of the catheter
- 10 set according to the invention as it is difficult to force the catheter down into the lower part of the package especially when the user has reduced motility of the hands, and when the catheter is still present in the narrow part of the package it is almost impossible for the user to tie a liquid-tight knot on the narrow part as recommended in the instructions for use of Convene EasiCath Set from
  - 15 Coloplast A/S.

- Reference is made to fig. 3 showing an embodiment of the package of the invention having a sealing device at the exterior side of the package. In order to solve the above problem and render it easier for the user to transport a filled package it is preferred to use a different kind of closing system as e.g. a system
- 20 where the upper end of the catheter set package is closed with a piece of gummed tape or tied together by extra added parts.

- A very effective sealing device comprises three pieces of film or paper and is illustrated in figures 3 - 5. Figure 4 shows how the three pieces are arranged in connection with each other: an upper piece 11, a middle piece 12 and a lower
- 25 piece 13. The upper piece is non-adhesive on the outer surface and adhesive on the surface facing the package, one end of this piece is adhered to the package and the other end is adhered to the middle piece 12. The middle piece 12 is non-adhesive on both surfaces and both surfaces are made of a material which makes it possible to release it from adhesive surfaces without spoiling the
  - 30 adhesiveness. The middle piece 12 is preferably considerably larger than the



one end of the upper piece 11 it is covering as this makes it easier to grab and remove the middle piece 12 from the package. The middle piece may e.g. be made from siliconised paper. The surface of the middle piece facing 12 away from the upper piece 11 is facing the lower piece 13. The lower piece 13 is  
5 adhesive on both surfaces, one surface secure the lower piece 13 to the package and the other surface secure the lower piece 13 to the middle piece 12.

Before the closing device is used for securing and sealing the proximal end of the catheter set, the three pieces are placed on the front or the backside of the package, they are all three releasably glued together as each of them get contact  
10 with at least one adhesive surface. When the user need to close the package he pulls the middle piece 12 and the upper end of the upper piece 11 backwards, by this action the middle piece 12 is released from the lower piece 13 (only the movement of the upper piece 11 is indicated in the figure). After the user has remove the middle piece 12 from the upper piece 11, the user places the open  
15 end of the catheter set on the lower piece, this will secure the position of the open end, and then the user covers the open end of the package with the upper piece. The open end of the package is now secured between the upper and the lower piece.

Figure 5 shows a sectional view of a package with the sealing device in a closed  
20 position.

**CLAIMS**

1. A catheter set comprising a catheter and a package for storing of the catheter before use and for collecting or discharging urine, CHARACTERISED IN that the catheter has a proximal part to be inserted into the urethra and a distal part in the  
5 form of a tubular section having an inner diameter at least as large as the inner diameter of the part of the proximal part of the catheter.
2. A catheter set according to claim 1, CHARACTERISED IN that the proximal part of the catheter has a hydrophilic coating.
3. A catheter set according to claim 1 or 2, CHARACTERISED IN that the set  
10 comprises a wetting fluid integrated into the package.
4. A catheter set according to any of claims 1 - 3, CHARACTERISED IN that the catheter comprises a sealing part for providing a seal between the catheter and the package during use.
5. A catheter set according to claim 4, CHARACTERISED IN that the sealing  
15 part is separating the proximal part of the catheter and the tubular distal part.
6. A catheter set according to any of claims 1 - 5, CHARACTERISED IN that the tubular distal part of the catheter has an inner diameter larger than the inner diameter of the proximal part of the catheter.
7. A catheter set according to any of claims 1 - 6, CHARACTERISED IN that the  
20 tubular part is made from an extrudable, mouldable material such as a polyolefin such as polyethylene (PE) or polypropylene (PP) or a copolymer of polyethylene such as ethylene vinyl acetate (EVA) or polyvinyl chloride (PVC) or polyvinylidene chloride.
8. A catheter set according any of claims 1 - 7, CHARACTERISED IN that the  
25 tubular distal part of the catheter is transversely corrugated.

9. A catheter set according to any of claims 1 - 8, CHARACTERISED IN that th  
package has an elongated narrow part at the end where the catheter exits the  
package and with a broader container part.

10. A catheter set according to any of claims 1 - 9, CHARACTERISED IN that  
5 the package is provided with one or more sealing devices on the exterior side of  
the package.

11. A catheter set according to claim 10, CHARACTERISED IN that the sealing  
device comprises an adhesive sheet adhered to the package.

**ABSTRACT****A catheter set**

- A catheter set comprising a catheter and a package for storing of the catheter before use and for collecting or discharging urine wherein the catheter has a
- 5 proximal part to be inserted into the urethra and a distal part in the form of a tubular section having an inner diameter at least as large as the inner diameter of the part of the proximal part of the catheter prevents a blocking of the free flow of urine from the urethra into the package.

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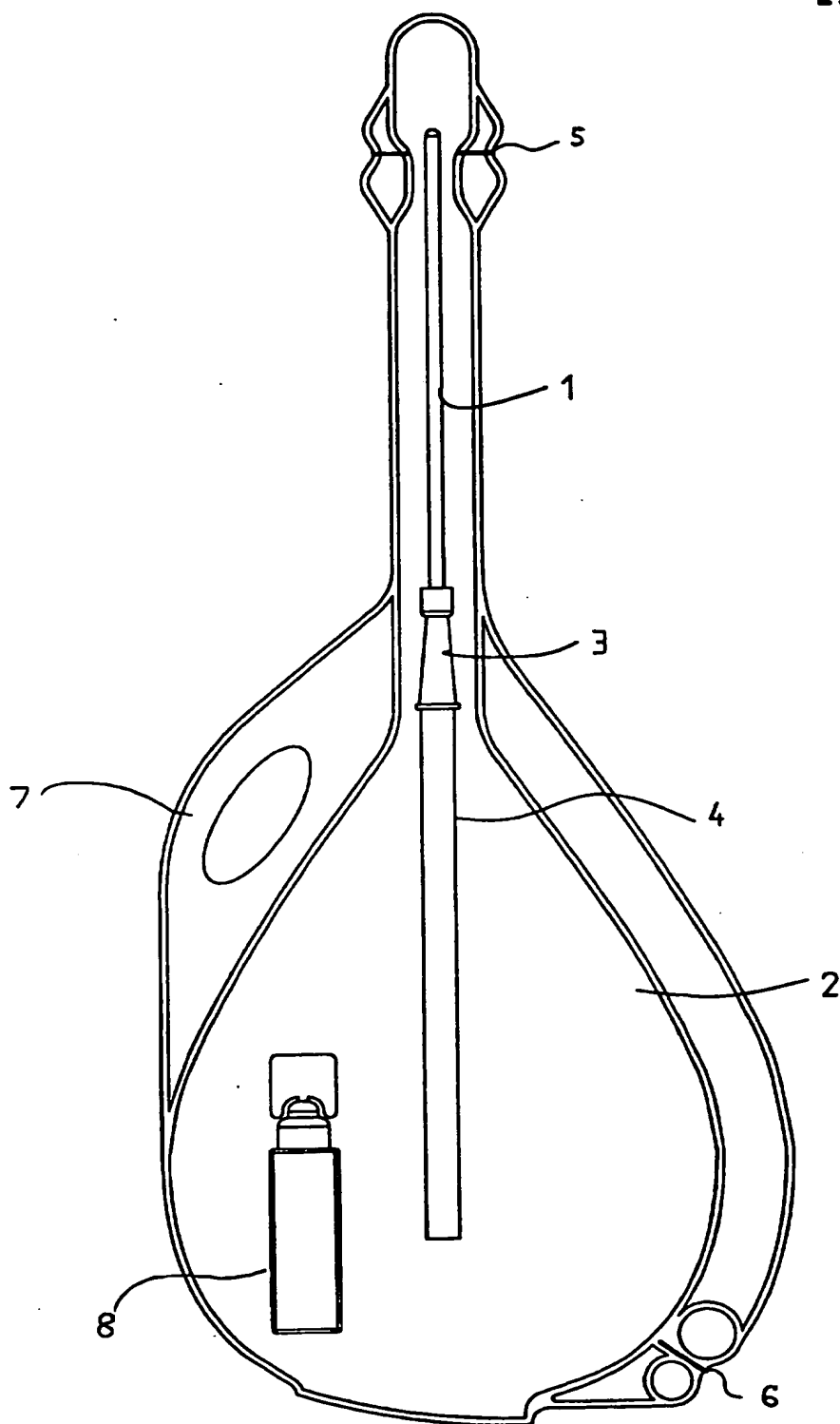


Fig. 1

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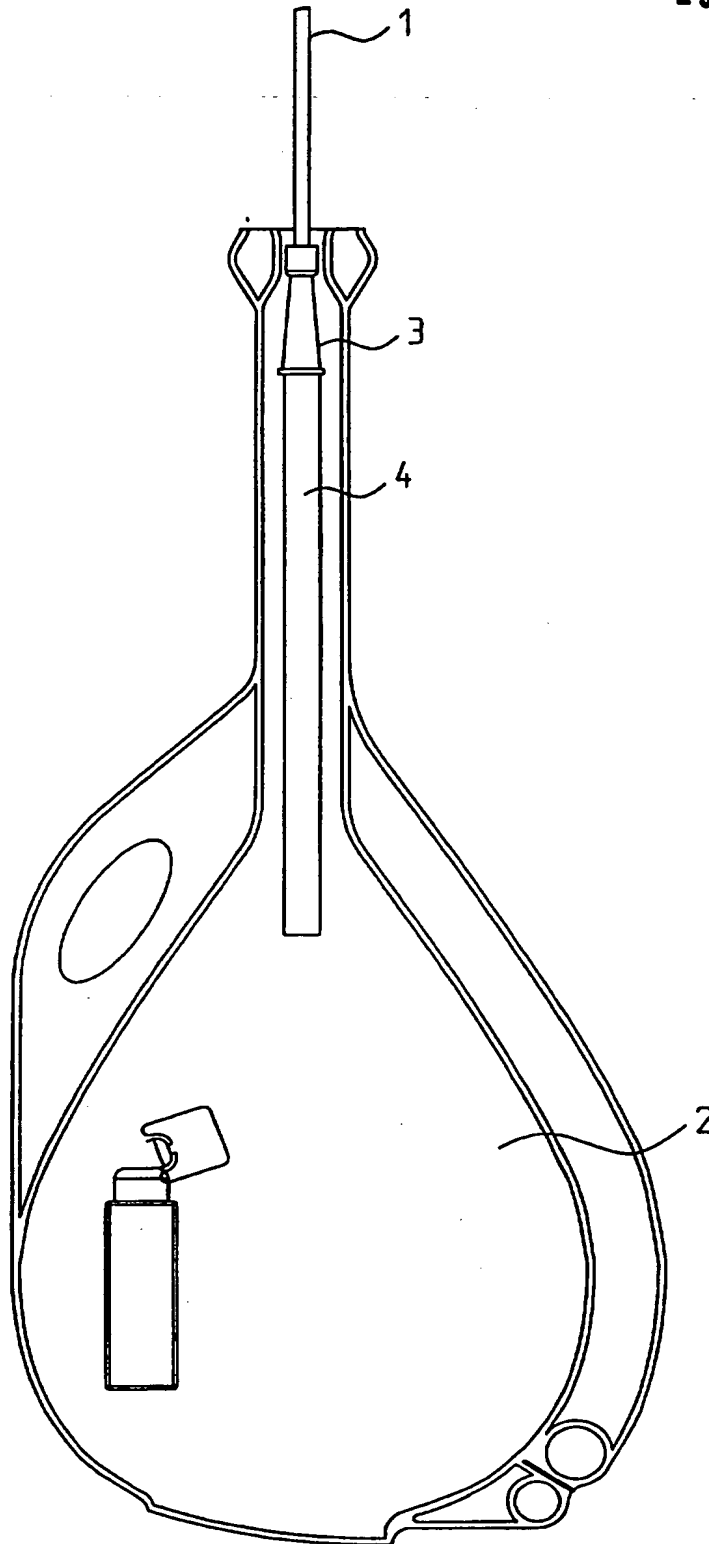


Fig. 2

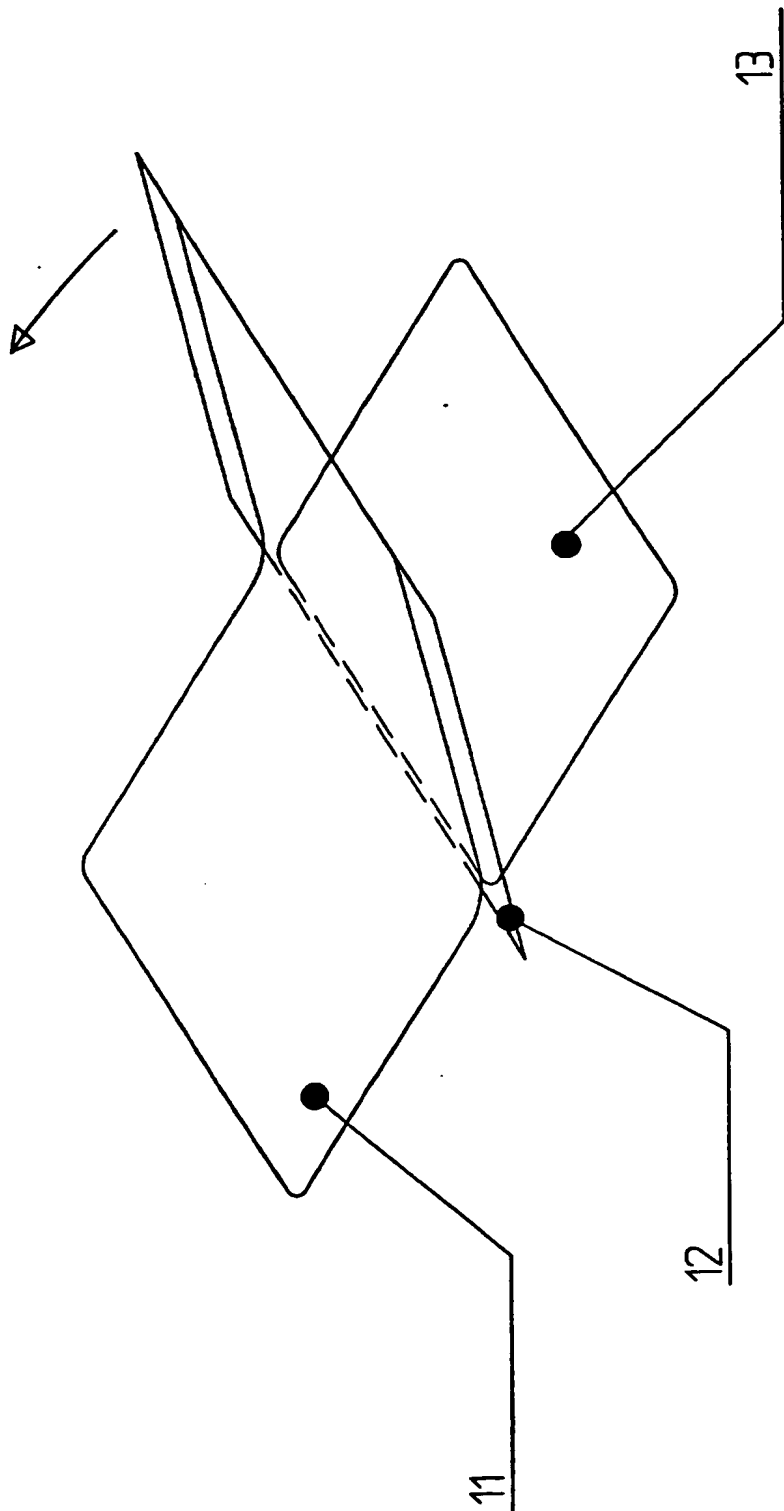


FIG. 4

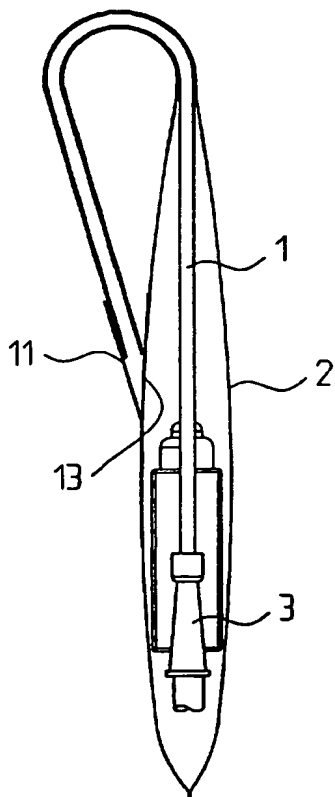


Fig. 5

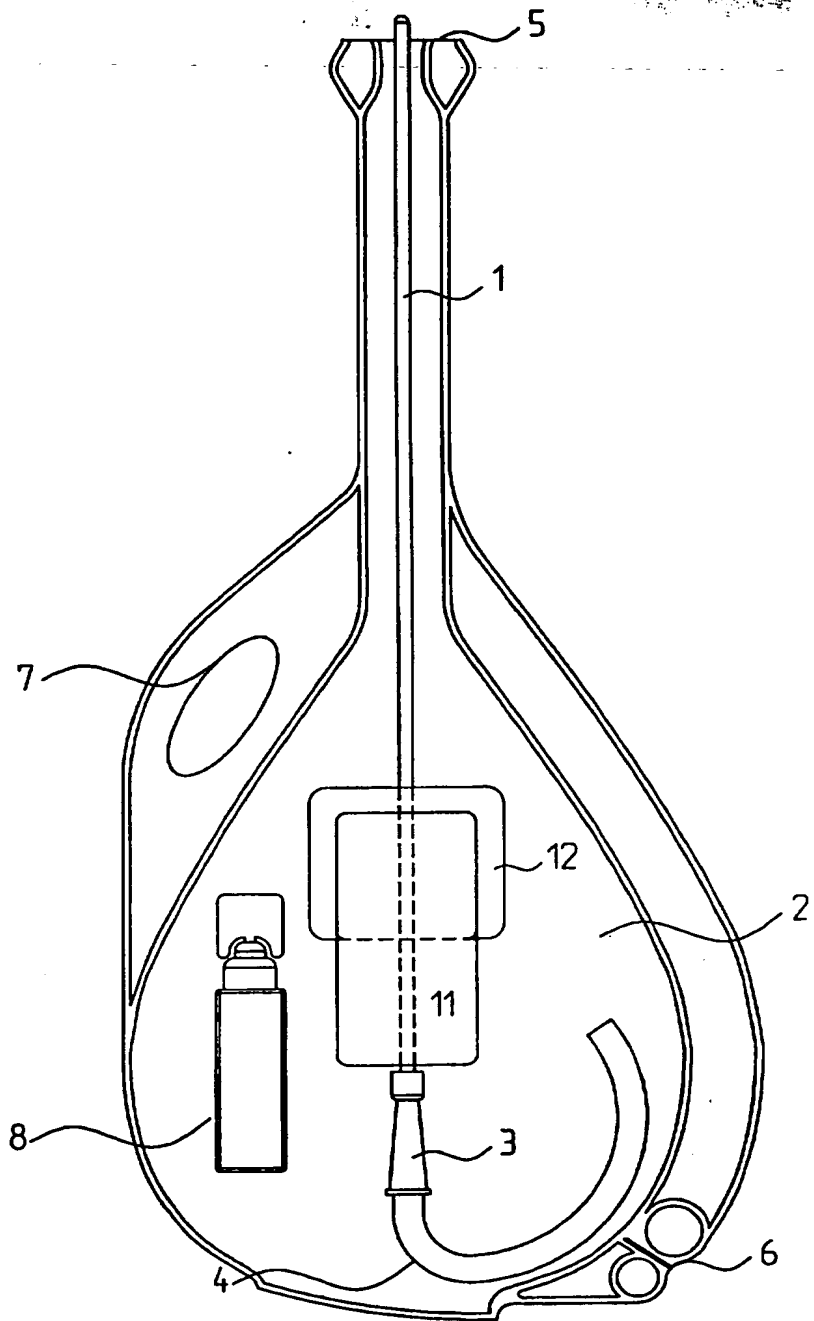


Fig. 3